

**UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**

**CITY OF HUNTINGTON,  
Plaintiff,**

**v.  
AMERISOURCE BERGEN DRUG  
CORPORATION, et al.,  
Defendants.**

**Civil Action No. 3:17-cv-01362**

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**CABELL COUNTY COMMISSION,  
Plaintiff,**

**v.  
AMERISOURCE BERGEN DRUG  
CORPORATION, et al.,  
Defendants.**

*Consolidated case:*  
**Civil Action No. 3:17-cv-01665**

**PLAINTIFFS' REPLY MEMORANDUM OF LAW IN SUPPORT  
OF THEIR MOTION TO LIMIT THE TESTIMONY  
OF DEFENDANTS' EXPERT TRICIA WRIGHT, M.D.**

Dated: October 30, 2020

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## ARGUMENT

### I. DR. WRIGHT IS UNQUALIFIED TO OFFER OPINIONS ABOUT CHILDREN WITH NAS

In their arguments in opposition to Plaintiffs' motion, Defendants fail to show that Dr. Wright's education, training, experience, or study qualify her to opine about the subjects Plaintiffs seek to exclude. *See Maryland Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998) (proponent of expert testimony has the burden of coming forward with evidence from which the trial court may determine that testimony is admissible under Rule 702 and *Daubert*). In particular, Dr. Wright lacks education, training, or experience that would qualify her to offer an opinion that neonatal abstinence syndrome ("NAS") is "a temporary and treatable condition"; that "NAS is a highly heterogeneous condition"; that because of "the largely unfounded fear of severe consequences, the majority of infants in this country have traditionally been over-treated, usually in the neonatal intensive care units, which is expensive, and in most cases, unnecessary and counterproductive"; that "[t]he majority of [NAS] children have gone on to live normal lives"; or that "[t]he problems [NAS children] have stem from the treatment of their mothers as criminals, the stigma they faced, and the poverty and poor situations in which they were raised." Wright Report [ECF 1082-1] at 4, 5, 9, 11. As an obstetrician/gynecologist, Dr. Wright treats pregnant women with substance abuse problems. She has no demonstrable expertise, education, training or skill in diagnosing, treating, or opining about the prognosis of children born with NAS.

Defendants argue that Dr. Wright is qualified to offer the opinions that Plaintiffs seek to exclude because "[p]art and parcel of her care of pregnant women who have substance abuse problems is counseling them about the potential impact of their substance use on their babies." Def. Br. [ECF 1098] at 3. But Dr. Wright's own description of her counselling role is not quite as expansive as Defendants suggest. She states:

I have counseled women on [i] the effects of opioids on pregnancy, [ii] the need for treatment with medication as addiction treatment (MAT), as well as [iii] the [a] incidence, [b] prevention, and [c] treatment of neonatal withdrawal. For many years, my partners and I at the University of Hawaii delivered the babies and cared for their mothers in the hospital after delivery. It is important for the mothers [iv] to understand NAS and, [v] if it occurs, for them to play an active role in the support and care of their babies through the withdrawal process.

Report [ECF 1082-1] at 2 (brackets added).

Thus, her counselling focuses on the risks and benefits to the fetus of treating the *expectant mother* for addiction ([i] & [ii]). It covers the incidence of NAS (*i.e.*, its rate of occurrence) ([iii] [a]) and the prevention of NAS (*i.e.*, by discontinuing or limiting the use of opioids) ([iii] [b]), but neither of those topics has anything to do with whether NAS is temporary or treatable or what its long-term effects are. As for her counselling about “treatment of neonatal withdrawal” ([iii] [c]), whether that experience qualifies her to opine about the treatment of NAS depends on the nature of the counselling she does. For example, if she counsels her patients that they should seek advice and treatment from an experienced physician who treats NAS—*i.e.*, someone other than Dr. Wright—that would not suggest that she is qualified to offer opinions about the treatment of NAS. But the only light her Report sheds on the kind of counsel she gives about treatment is that she conveys to mothers that it is important for them to understand NAS ([iv]) and to play an active role in the support and care of their babies if it occurs ([iv])—such advice hardly qualifies as expert advice; it is just common sense. Put simply, based on her own description of her counselling, there is no reason to believe Dr. Wright is qualified to offer expert opinions about the long-term prognosis for children suffering with NAS, whether NAS babies are “over-treated,” or whether they go on “to live normal lives.” *Id.* at 9, 11.

Defendants’ reliance on Dr. Wright’s peer-reviewed publications will not withstand scrutiny. For example, Dr. Wright was just one of *fifteen* co-authors of a report describing what had been discussed at a joint workshop of the Society for Maternal-Fetal Medicine of the American

College of Obstetricians and Gynecologists and the American Society of Addiction Medicine. Defendants point to a section of the report that deals with fetal and neonatal effects of Medication Assisted Therapy; this section discusses the lack of proven long-term effects from exposure to methadone or buprenorphine during pregnancy as well as the need for maternal counseling about NAS by prenatal care providers. Defendants' Exhibit B [ECF 1098-2] at B17-18. But that section—to which Dr. Wright does not claim to have contributed—relates to the long- and short-term risks and benefits to the child of treating the expectant mother with medication to assist withdrawal, not the post-natal treatment of infants born with NAS. To the extent that section relates to infants, it focuses not on the diagnosis, treatment, or prognosis of children with NAS but rather on the lack of proven long-term effects on the child from medication-assisted treatment of the mother. The other publications cited by Defendants are even less on point. *E.g.*, *Detection of opioids in umbilical cord lysates: an antibody-based rapid screening approach*, TOXICOL. MECH. METHODS., 2019 Jan; 29(1):35-42.

Defendants argue that Dr. Wright “has educated her peers on risks, including NAS, to fetuses and children from maternal substance use disorders,” and that may be so, but that does not qualify her to opine about the long term prognosis for NAS babies. One of the presentations Defendants cite has a *title* that seems to support Dr. Wright's qualifications to discuss long term effects: *NAS is Temporary, FAS is Permanent: Understanding Alcohol Use in Women*, Conference Presentation at the American College of Obstetricians and Gynecologists Annual Clinical Meeting, Nashville, TN, May 2019; Stanford University Grand Rounds, Stanford, CA, September 2018. But, as became clear in her deposition, the focus of that talk was not on the fact that NAS is temporary; rather, it was on the fact that fetal alcohol syndrome is permanent:

Q. And can you tell me generally about what your message is or the conclusions you make in that presentation about NAS being temporary?

A. Yes. So my conclusions are that fetal -- or fetal alcohol syndrome is a permanent, lifelong condition caused by alcohol use during pregnancy, and it often coexists with neonatal abstinence syndrome, so that for the addiction medicine providers, I am having them focus and looking for co-occurring alcohol use along with the opioid use.

And for the OB/GYNs that focus -- I'm trying to get them to screen for alcohol use during pregnancy, which is much more harmful than opioid use.

Deposition [ECF 1081-2] at 78:22-79:13.

While Dr. Wright did go on to claim that her presentation cites studies that support her opinion that NAS is temporary, neither in her Report nor her deposition did she cite any such study, and none is identified in Defendants' opposition to Plaintiffs' motion. During her deposition, Plaintiffs requested production of the presentation, *id.* at 80, but to date Defendants have failed to produce it. If it actually supported their position, Defendants would doubtless have included it among the exhibits they filed in opposition to Plaintiffs' motion, but they did not do so.

Defendants point out that Dr. Wright was the editor of a 2018 textbook, *Opioid-Use Disorders in Pregnancy: Management Guidelines for Improving Outcomes*, the final two chapters of which relate to newborns, including one relating to NAS. Defendants have supplied only the table of contents, however, not the chapter on NAS. Thus the record does not reflect what the chapter actually says. What the record does reflect is that the chapter, whatever it says, was not authored by Dr. Wright. *See* Exhibit C [ECF 1098-3]. That Dr. Wright edited the book does not demonstrate that she is qualified to testify as an expert on the subject of each or any particular chapter—especially chapters not before the Court. Likewise, her service as an editorial board member of the MATERNAL AND CHILD HEALTH JOURNAL, does not qualify her as an expert on each or any particular topic that may have been the subject of a paper that appeared in that publication.

Defendants also note that Dr. Wright is a peer reviewer for the JOURNAL OF PERINATOLOGY, but they acknowledge that perinatology is the medical specialty concerned with the care of the

mother, fetus, and infant during the period immediately surrounding birth. Her experience as a peer reviewer of that journal might qualify her to offer opinions beyond her expertise in obstetrics and gynecology—and extending to perinatology—but it does not qualify her to opine beyond perinatology about the diagnosis or long term effects of, or treatment for, NAS.

In short, the record simply does not support Defendants’ argument that Dr. Wright (i) “has had training and experience with NAS,” (ii) “has had many years of clinical experience with mothers and their babies,” (iii) “has published articles and peer-reviewed the articles of others” relating to NAS, and (iv) “has done a thorough review and evaluation of the NAS literature.” Def. Br. [ECF 1098] at 7.

## **II. DR. WRIGHT’S OPINIONS ABOUT NAS CHILDREN LACK A RELIABLE FOUNDATION**

Even if Dr. Wright’s expertise as an obstetrician/gynecologist were sufficient to qualify her to offer opinions about NAS, as demonstrated in Plaintiffs’ opening brief, her opinions on that subject lack a reliable foundation and should be excluded in any event. Defendants assert that,

In order to effectively counsel her patients about the potential short-term and long-term consequences of their substance use on their babies, Dr. Wright must be readily familiar with the published literature and clinical guidelines regarding the mother-child dyad and how substance use during pregnancy impacts both mother and child.

Def. Br. [ECF 1098] at 7.<sup>1</sup> But neither Defendants nor Dr. Wright contend that she performed a literature search *in order to form her opinions in this case*.<sup>2</sup> Defendants note that Dr. Wright included many articles in her list of materials she considered, but they nowhere address the fact

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<sup>1</sup> As previously noted, Dr. Wright’s patients are pregnant women, not babies.

<sup>2</sup> Dr. Wright testified that her opinions were based both on her clinical experience and her “extensive review of the literature,” Deposition [ECF 1081-2] at 86:10-11, but that “extensive review” was not a literature review focused on the treatment of NAS; she was referring to both her materials considered and/or relied upon list as well as “many, many things that I have read over the years that I can’t – that form the basis of my opinions that I can’t begin to, you know, write them all down.” *Id.* at 88:3-7.



that her Report fails to specify a single article that supports the opinions that Plaintiffs seek to exclude (or indeed any of the opinions in her Report),<sup>3</sup> fails to describe the methodology through which her list of materials considered was assembled,<sup>4</sup> and fails to demonstrate that she considered, and accounted for, any literature that reaches a contrary conclusion. *See In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.*, 26 F. Supp. 3d 449, 459-60 (E.D. Pa. 2014) (where expert failed to address contrary studies and explain his disagreement with them, opinions was properly excluded); *see also In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices & Prods. Liab. Litig.*, 174 F. Supp. 3d 911, 930 (D.S.C. 2016) (excluding opinions where expert “did not review the ‘totality of the literature,’ and [proponents] have made no showing whatsoever that he performed any search to obtain relevant literature, rather than cherry-picking studies that supported his conclusion”); *Tyree v. Bos. Sci. Corp.*, 54 F. Supp. 3d 501, 520-21 (S.D. W. Va. 2014); *In re Bextra & Celebrex Mktg. Sales Practices & Prods. Liab. Litig.*, 524 F. Supp. 2d 1166, 1176 (N.D. Cal. 2007); *In re Rezulin Prods. Liab. Litig.*, 369 F. Supp. 2d 398, 425-26 (S.D.N.Y. 2005). The most that can be said here is that Dr. Wright has read isolated articles that touch on the subject of NAS, but that is far from a reliable basis for an expert opinion.

Furthermore, an expert who relies on literature must be qualified to analyze and assess the material reviewed. *See In re Neurontin Mktg., Sales Practices, & Prod. Liab. Litig.*, 612 F. Supp. 2d 116, 157-58 (D. Mass. 2009); *cf. Tyree*, 54 F. Supp. 3d at 567-68 (physician who was himself well-qualified qualified to diagnose and treat the relevant condition was permitted to rely on the

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<sup>3</sup> Defendants do not deny that there is not a single citation anywhere in the Report to anything. *See* Report [ECF 1081-1]; *see also* Deposition [ECF 1081-2] at 110:16-19. Because of the lack of specific citations, Dr. Wright’s Report is not in compliance with Fed. R. Civ. P. 26(a)(2), in that it fails to disclose the “basis and reasons” for the opinions set forth in it.

<sup>4</sup> Some of the materials on Dr. Wright’s materials considered list were selected by her and some were provided to her by defense counsel. Deposition [ECF 1081-2] at 88:15-22.

medical records of other physicians).<sup>5</sup> Defendants distinguish the facts of *Neurontin*, see Def. Br. [ECF 1089] at 6-7, but fail to address the principle for which Plaintiffs cited it: an expert must have appropriate expertise to rely on a literature search in order to form her opinions. Where, as here, the witness is unable to bring her own expertise to her review of materials in the field, she can do nothing more than parrot the views of others as reflected in the literature. Such second-hand opinions are not reliable and should be excluded. See *Dura Automotive Systems of Indiana, Inc. v. CTS Corp.*, 285 F.3d 609 (7th Cir. 2002) (“A scientist, however well credentialed he may be, is not permitted to be the mouthpiece of a scientist in a different specialty”).

### CONCLUSION

The Court should limit the testimony of Dr. Wright by excluding her proposed testimony pertaining to babies with NAS.

Dated: October 30, 2020

Respectfully submitted,

THE CITY OF HUNTINGTON

CABELL COUNTY COMMISSION

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<sup>5</sup> The physician in *Tyree* had performed over a thousand pelvic floor surgical procedures, including over 200 surgeries dealing with complications related to synthetic mesh. *In re Ethicon, Inc., Pelvic Repair Sys. Prod. Liab. Litig.*, No. 2:12-CV-4301, 2014 WL 186872, at \*20 (S.D.W. Va. Jan. 15, 2014). Dr. Wright has no comparable experience diagnosing or treating NAS babies that would qualify her to evaluate literature regarding that subject.

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### **CERTIFICATE OF SERVICE**

I certify that on October 30, 2020, a copy of the foregoing was filed electronically. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system. This filing will also be served on all parties by email to: [Track2OpioidDefendants@ReedSmith.com](mailto:Track2OpioidDefendants@ReedSmith.com) and [mdl2804discovery@motleyrice.com](mailto:mdl2804discovery@motleyrice.com).

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